

**IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF ILLINOIS**

**IN RE: TESTOSTERONE REPLACEMENT  
THERAPY PRODUCTS LIABILITY  
LITIGATION**

**THIS DOCUMENT RELATES TO:**

ALL CASES IN WHICH AUXILIUM IS A DEFENDANT.

**Case No. 1:14-cv-1748**

**MDL No. 2545**

**Hon. Matthew F. Kennelly**

**Auxilium Pharmaceuticals, Inc.'s Brief  
in Opposition to Plaintiffs' Steering  
Committee's Motion to Compel  
Privilege Log Information**

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## I. INTRODUCTION

In their motion to “Compel Privilege Log Information,” the Plaintiffs’ Steering Committee (“PSC” or “Plaintiffs”) challenges the assertion by Auxilium Pharmaceuticals, Inc. (“Auxilium”) of attorney-client privilege with respect to 15 of the 10,645 documents produced by Auxilium on behalf of an independent contractor (Heartbeat Ideas) to which Auxilium outsourced certain functions relating to the marketing of its testosterone replacement therapy (“TRT”) product, Testim®. Plaintiffs’ challenge is based on their argument that a corporation cannot assert a privilege to communications to “third-parties.” *See* Pls.’ Br. 1 (“Defendant waived the privilege by disclosing the documents to a third-party vendor”). In particular, Plaintiffs argue that even in a corporate setting, a communication is only privileged when it is sent (1) directly to or from an attorney and (2) only to “employees” of the corporation asserting the privilege.

The PSC and Auxilium agree that Pennsylvania, the law of Auxilium’s domicile, governs this dispute. The PSC’s narrow definition of privilege, however, betrays a fundamental misunderstanding of the well-established law in Pennsylvania that for corporations, such as Auxilium, the attorney-client privilege extends to communications between its attorneys and agents or employees.<sup>1</sup> Contrary to plaintiffs’ argument, under Pennsylvania law, the focus of the attorney-client privilege analysis is not on whether an attorney is directly identified on the

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<sup>1</sup> *See, e.g., In re Condemnation by City of Philadelphia in 16.2626 Acre Area*, 981 A.2d 391, 396 (Pa. Commw. 2009) (finding that the attorney-client privilege extends to communications between a corporation’s attorneys and agents or employees authorized to act on the corporation’s behalf); *Custom Designs & Mfg. Co. v. Sherwin-Williams Co.*, 39 A.3d 372, 376 (Pa. Super. 2012) (finding that “communications by corporate employees to corporate counsel may fall within the scope of the attorney-client privilege when they are kept confidential and when they are made at the behest of counsel and with the goal of furthering counsel’s provision of legal advice to the client, the corporation.”).

communication or whether every person to whom the communication was made was a direct employee of the corporation asserting the privilege. Instead, Pennsylvania recognizes that as an inanimate entity, a corporation must act through its representatives, and as long as the representatives are acting within the scope of their employment or agency, the attorney-client privilege attaches. The proper focus of the analysis is on whether the communications were made for the purposes of providing or requesting legal advice and whether those communications were intended to be confidential. Accordingly, as demonstrated below, when the appropriate analysis is applied to the communications at issue here, Auxilium's claim of privilege should be sustained.

## **II. STATEMENT OF FACTS**

On February 4, 2015, the PSC served Heartbeat Ideas ("Heartbeat"), with a subpoena seeking the discovery of documents and things related to Heartbeat's work as agent or independent contractor with respect to the marketing of Testim®. Heartbeat is a marketing consultant with expertise in the health care industry that was retained by Auxilium in 2009 to assist with and perform marketing functions with respect to Testim®. These marketing functions would normally be handled by a pharmaceutical company's in-house marketing team but, because Auxilium was not sufficiently staffed to handle these functions, Auxilium outsourced them to Heartbeat.

### **A. Marketing Within the Pharmaceutical Industry.**

It is often not cost efficient for smaller companies, like Auxilium, to employ a sufficiently large in-house team to manage all aspects of marketing campaigns for its products. As a result, it is common even for pharmaceutical companies to outsource the typically in-house functions of creating, developing, and implementing marketing campaigns to consultants like Heartbeat. *See In re Flonase Antitrust Litig.*, 879 F. Supp. 2d 454, 460 (E.D. Pa. 2012) (finding

that corporations are increasingly conducting their business through a variety of independent contractors retained for specific purposes). Creating a marketing campaign for a pharmaceutical product requires compliance with a complicated and sophisticated regulatory framework, including the regulatory restrictions and technological limitations of the distribution channels (e.g., television ads, magazines, journals, other print media, and other visual media).

Accordingly, this work requires a high level of expertise and significant legal oversight. *See, e.g., King Drug Co. of Florence v. Cephalon, Inc.*, Nos. 2:06-CV-1797, 2:08-cv-2141, 2013 WL 4836752, at \*6 (E.D. Pa. Sept. 11, 2013) (recognizing that marketing and business strategy within the pharmaceutical industry are inextricably linked to regulatory and legal issues).

Because Auxilium delegated responsibility for creating and developing much of the marketing material for Testim® that entered the public domain to Heartbeat, it was necessary for attorneys within the Auxilium legal department to communicate legal advice to Heartbeat and to alert Heartbeat to potential legal and regulatory concerns, just as they would to any employee performing the same functions in-house. Particularly within the highly regulated pharmaceutical industry in which every communication to consumers or healthcare providers can have significant legal and regulatory ramifications, the marketing, regulatory and legal teams are inextricably linked. *See, e.g., King Drug*, 2013 WL 4836752, at \*6 (E.D. Pa. Sept. 11, 2013) (recognizing that marketing and business strategy within the pharmaceutical industry are inextricably linked to regulatory and legal issues). This is precisely why consultants like Heartbeat become embedded members of the “marketing team” for the pharmaceutical companies that retain them, and as a result, they are treated as “employees” or “authorized agents” of the company for the limited scope of their retention. They attend meetings, communicate directly with other employees, are given a substantial amount of discretion, are

integral to the development of the marketing campaigns and are subject to the same confidentiality requirements as those that apply to direct employees of the company

**B. Heartbeat Played a Significant Role in the Creation, Development and Implementation of the Testim® Marketing Campaign.**

In 2009, Auxilium was a relative newcomer to the pharmaceutical industry and was also relatively small in comparison to its competitors. Auxilium only marketed two products at the time: Xiaflex®, indicated for treatment of adult Dupuytren's contracture, and Testim®, the testosterone replacement therapy ("TRT") product relevant to this litigation.

Auxilium initially retained Heartbeat in May 2009 and the relationship continued through 2012. *See, e.g.*, Ex. 1, HEARTBEATS-MDL2545-00015959; Ex. 2, HEARTBEATS-MDL2545-00017282. When first retained in 2009, Heartbeat was delegated the responsibility for developing the creative content for the Testim® website, rationalizing existing content, reworking the website and creating new content. *See*, Ex. 3, HEARTBEATS-MDL2545-00023291-92. In 2010, Auxilium later expanded Heartbeat's role, giving the company responsibility in the development of a digital marketing plan for Testim®, including development of a direct-to-consumer campaign. Ex. 17, HEARTBEATS-MDL2545-00023179. Auxilium also delegated work to Heartbeat with respect to the development of an electronic customer relationship management program to improve the performance of the Testim® website. *See* Ex. 7, HEARTBEATS-MDL2545-00017478. Heartbeat continued to develop the content and direction of the Testim® digital marketing campaign into 2012. *See* Ex. 2, HEARTBEATS-MDL2545-00017282; Ex. 4, Heartbeats MDL-2545-00017973-74.

During the four years that Auxilium delegated responsibility for the development and direction of the Testim® digital marketing campaign to Heartbeat, Heartbeat was fully integrated into the team of employees working on Testim® ("Team Testim®") and was subject to the same



confidentiality agreements that applied to Auxilium's own employees. *See* Ex. 5, HEARTBEATS-MDL2545-00022433; Ex. 7, HEARTBEATS-MDL2545-00017493. Bringing Heartbeat onto Team Testim® enabled Auxilium to effectively triple its marketing resources by relying on the expertise of the experienced team of nine Heartbeat employees devoted to Testim®, without the need to immediately hire and train an entirely new group of marketing employees. *See* Ex. 5, HEARTBEATS-MDL2545-00022433; Ex. 6, HEARTBEATS-MDL2545-00000046.

Auxilium and Heartbeat communicated regularly regarding the creation of the marketing campaign for Testim®, the development of promotional pieces and the implementation of the actual marketing campaign. Because sensitive materials and information were shared among Heartbeat and Auxilium, they agreed that all information would remain confidential and agreed not to disclose such communications without the permission of the other party. *See e.g.*, Ex. 18, Declaration of Kristin Kennedy; Ex. 7, HEARTBEATS-MDL2545-00017493.

**C. Auxilium Maintained Responsibility for Legal and Regulatory Compliance**

Although Auxilium delegated creative responsibility for the development of a digital marketing campaign to Heartbeat, it did not delegate to Heartbeat every function relevant to the dissemination of that material, such as legal compliance. As a result, all new creative materials generated within Heartbeat were the subject of an integrated process that consisted of a close collaboration with Auxilium employees on a daily or weekly basis to refine the materials, to address any potential legal or regulatory concerns and to insure compliance with all legal and regulatory requirements and restrictions. *See e.g.*, Ex. 18, Declaration of Kristin Kennedy; Ex. 8, HEARTBEATS-MDL2545-00022581-87.

An important part of that integrated process was Heartbeat's participation in meetings with Auxilium's Promotional Review Committee ("PRC"), a committee consisting of

representatives from Auxilium's legal, medical, regulatory and marketing departments. Each representative was charged with the responsibility of reviewing every draft promotional piece and providing comments, suggestions or revisions. Promotional pieces were not permitted to leave Auxilium unless they were approved by the PRC, making the meetings a critical place for each department to collaborate to produce materials and content. The goal of the PRC was to ensure that all promotional pieces complied with all regulations and laws, contained medically accurate information and remained consistent with Auxilium's brand messaging. *See e.g.*, Ex. 18, Declaration of Kristin Kennedy. As members of Team Testim®, Heartbeat regularly attended and participated in the PRC meetings. *See* Ex. 9, HEARTBEATS-MDL2545-00004187. Heartbeat received instructions and advice directly from Auxilium in-house attorneys and other key members of the PRC regarding any changes that needed to be made to marketing materials. After receiving feedback from the PRC, Heartbeat would make the suggested changes and go through another round of revisions. *See* Ex. 10, HEARTBEATS-MDL2545-00005518-20; Ex. 11, HEARTBEATS-MDL2545-00022786-90. Heartbeat worked in tandem with Auxilium employees to anticipate potential issues the PRC might raise and would recommend changes and/or further review of the pieces in question before submitting them to the PRC. *See e.g.*, Ex. 18, Declaration of Kristin Kennedy; Ex. 10, HEARTBEATS-MDL2545-00005518-20; Ex. 12, HEARTBEATS-MDL2545-00002220.<sup>2</sup>

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<sup>2</sup> Heartbeat was also responsible for providing direction and feedback to TrialCard, a third-party vendor Auxilium used for marketing and customer support services. Because TrialCard materials had to be approved by the PRC, Auxilium relied on Heartbeat to revise TrialCard's work product, and to relay ideas and concerns from Auxilium's brand team, as well as feedback from the PRC and Auxilium's in-house attorneys. *See* Ex. 14, HEARTBEATS-MDL2545-00009272-76; Ex. 15, HEARTBEATS-MDL2545-00008887-90.

In addition to meetings with the PRC, employees of Heartbeat and Auxilium on Team Testim® routinely met at Heartbeat's offices to discuss next steps and to allocate tasks, some of which were assigned jointly to Heartbeat and Auxilium employees. *See* Ex. 13, HEARTBEATS-MDL2545-00022213-14. Among other things, their joint tasks included confirming PRC approval of marketing materials. *See Id.*

**D. The Challenged Privileged Documents.**

After receiving the subpoena at issue, and in keeping with its confidentiality and notice obligations, Heartbeat contacted Auxilium's counsel. Given the historical structure of their relationship and Heartbeat's creative responsibility for the materials within the scope of the subpoena, Auxilium and Heartbeat agreed that Heartbeat would identify the responsive documents within its possession, custody and control, and then Auxilium would review the identified documents for privilege and confidentiality. Auxilium, on behalf of Heartbeat, then produced in two rolling productions on March 25, 2015 and May 15, 2015 over 36,000 pages of responsive documents. Also on May 15, 2015, Auxilium, on behalf of Heartbeat, produced a log identifying only 15 privileged communications between Heartbeat and Auxilium (the "Privilege Log"), 11 of which were produced with redactions. The four completely withheld documents contain communications between Auxilium's in-house counsel and Heartbeat.

All of the communications at issue relate directly to marketing for Testim® and were within the scope of Heartbeat's employment. Moreover, all of the communications on the Privilege Log fall within two categories: (1) communications requesting legal advice from counsel regarding marketing materials for Testim®; or (2) communications conveying legal advice from counsel regarding marketing materials for Testim®. The privileged party identified on the Privilege Log or in the produced documents themselves is either Auxilium's in-house legal counsel or, more specifically, Isabel Duffy, who served as Senior Attorney for Auxilium

from 2008 through 2011. *See* Ex. 16, AUXILIUM\_MDL\_CORP\_000000428. Specifically, the documents can be subcategorized as follows:

- Log entries 7 and 8 refer to produced documents in which the direct communications between Isabel Duffy, an in-house lawyer at Auxilium, and Team Testim® employee were redacted.
- Log entries 1, 2, 3, 4, 5, 6, 9, 10, and 11 refer to produced documents in which legal advice from or to other attorneys in Auxilium's legal department regarding the marketing materials for Testim® were redacted.
- Log entries 12 through 15, were withheld completely because they contain the legal advice of Isabel Duffy regarding the marketing materials for Testim®.

Indeed, 4 of the 11 redacted documents contain identical redactions because many of the emails are merely later iterations of the same email chains. In fact, after accounting for email threads, Auxilium is claiming the privilege on only 11 unique communications among the thousands produced on behalf of Heartbeat.<sup>3</sup>

Accordingly, each of the withheld or redacted documents identified on the Privilege Log was a communication sent to or received by a member of Auxilium's in-house legal department. Plaintiffs now seek discovery of those 15 privileged communications.

### **III. ARGUMENT**

The PSC's argument challenging Auxilium's privilege claim betrays a fundamental misunderstanding of the scope and application of attorney-client privilege as applied to corporations under Pennsylvania law — the law of Auxilium's domicile that both parties agree is applicable to this dispute. The PSC challenges Auxilium's privilege claims on two grounds:

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<sup>3</sup> Log entries 1 and 2 are different iterations of the same email chain with identical redactions. Log entries 4, 5 and 6 are also different iterations of the same email chain with identical redactions. Similarly, log entries 7 and 8 are different iterations of the same email chain with identical redactions.

(1) that Pennsylvania law only protects direct communications between an attorney and client, and therefore, because the withheld communications are indirect communications, the attorney-client privilege does not attach; and (2) that Auxilium waived the privilege by communicating with its marketing consultant Heartbeat. Neither of the PSC's arguments are sufficient to defeat Auxilium's privilege claim. First, the attorney-client privilege as applied to corporations in Pennsylvania protects indirect communications as well as direct communications among employees and counsel. Second, in the case of indirect communications, the PSC has failed to demonstrate a valid claim of waiver. While the PSC argues that there is no Pennsylvanian state court squarely addressing the exact dispute at issue here — *i.e.*, whether the attorney-client privilege protects communications between a corporation's counsel and a marketing consultant retained by the corporation to act as the functional equivalent of its own employees — the federal court in the Eastern District of Pennsylvania has consistently addressed this issue and determined that such communications are protected. Further, the rationale behind the Eastern District of Pennsylvania's "functional equivalent" doctrine for the application of the attorney-client privilege is consistent with Pennsylvania law.

**A. The Court Should Apply Pennsylvania Law to Evaluate whether Privileged Communications between Auxilium and Heartbeat Are Protected by the Attorney-Client Privilege.**

Pennsylvania law should apply to Auxilium's privilege claims. Auxilium's principal place of business is in Pennsylvania and all of the legal communications at issue originated in Pennsylvania. The Consultant Agreement between Auxilium and Heartbeat is governed by Pennsylvania law, and all communications by Auxilium's in-house attorneys were made in Pennsylvania. *See* Ex. 7, HEARTBEATS-MDL2545-00017493-97. Moreover, the parties

agreed<sup>4</sup> that consistent with conflict of law principles, Pennsylvania should apply. *See, e.g., Montgomery Cnty. v. MicroVote Corp.*, 175 F.3d 296, 301 (3d Cir. 1999) (applying Pennsylvania privilege law in a diversity action arising under Pennsylvania law to communications made within Pennsylvania); *Santer v. Teachers Ins. & Annuity Ass’n*, No. 06-CV-1863, 2008 WL 821060, at \*1 (E.D. Pa. Mar. 25, 2008) (holding Pennsylvania privilege law governed dispute over communications originating in Pennsylvania); *see also* Fed. R. Evid. 501 (“[I]n a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision.”)

The pendency of this MDL in Illinois does not alter the conclusion that Pennsylvania — the law under which Auxilium operates — governs this analysis.<sup>5</sup> For example, Judge Herndon in *In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prod. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 1375011 (S.D. Ill. Apr. 12, 2011) held:

Where the communication at issue is between individuals foreign to the forum, whose relationship is centered outside of the forum, and whose communications regard subject matter not centered in the forum, a special reason exists for not applying the law of the forum and the law of the state with the most significant relationship to the communication should be applied.

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<sup>4</sup> The parties engaged in several meet-and-confer discussions regarding these documents and after sharing relevant case law agreed that Pennsylvania state law governs Auxilium’s privilege claims.

<sup>5</sup> The issues and facts surrounding Auxilium’s privilege claims bear no connection to Illinois other than the fortuity that the JPML authorized an MDL proceeding to take place in the Northern District of Illinois, the principal place of business of Auxilium’s chief competitor Abbvie Inc. (“Abbvie”). To apply Illinois law to Auxilium’s privilege claims “would not make a great deal of sense.” *See In re Watson Fentanyl Patch Prod. Liab. Litig.*, 977 F. Supp. 2d 885, 888 (N.D. Ill. 2013) (Kennelly, J) (finding that the MDL location, Illinois, was essentially an artificial forum created for purposes of convenience and efficacy).

With this analysis of the choice of applicable law to the privilege claims, the *Yasmin* court applied the law of the state with the most significant relationship to the communications — the state of defendant’s principal place of business — rather than the law of the state of the District Court to which the MDL proceeding was assigned. *See In re Yasmin and Yaz (Drospirenone) Mktg., Sales Practices and Prod. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 2462033, at \*1 (S.D. Ill. June 17, 2011) (applying New Jersey privilege law to assess Bayer’s, privilege claims).

**B. Auxilium’s Privilege Log as Well as the Produced Documents Adequately Express the Privilege Claim and Describe the Nature of the Withheld and Redacted Documents so that Plaintiffs May Assess That Claim.**

As the party asserting the privilege, Auxilium bears the burden to set forth sufficient facts showing that the privilege applies to the withheld communications. *See, e.g., Custom Designs*, 39 A.3d at 376 (finding that under Pennsylvania law, “the party invoking a privilege must initially ‘set forth facts showing that the privilege has been properly invoked’”) (quotation omitted); *Se. Pennsylvania Transp. Auth. v. CaremarkPCS Health, L.P.*, 254 F.R.D. 253, 259 (E.D. Pa. 2008) (“The party asserting the attorney-client privilege ‘bears the burden of proving that it applies to the communication at issue.’”) (citation omitted). This burden can be met by establishing through competent evidence — such as a declaration or through documents — that the communications are protected by the attorney-client privilege. *See Lefta Associates v. Hurley*, No. 1:09-CV-2487, 2011 WL 2456616, at \*6 (M.D. Pa. June 16, 2011) (finding that the privilege cannot be established by mere conclusory assertions). As the proponent, Auxilium need only show the following to invoke the protection afforded by the attorney-client privilege:

- 1) The asserted holder of the privilege is or sought to become a client;
- 2) The person to whom the communication was made is a member of the bar of a court, or his subordinate;

- 3) The communication relates to a fact of which the attorney was informed by his client, without the presence of strangers, for the purpose of securing either an opinion of law, legal services or assistance in a legal matter, and not for the purpose of committing a crime or tort; and
- 4) The privilege has been claimed and is not waived by the client.

*Red Vision Sys., Inc. v. Nat'l Real Estate Info. Servs., L.P.*, 108 A.3d 54, 62-63 (Pa. Super. 2015). Here, for each of the withheld communications, the Privilege Log and produced documents clearly demonstrate that: (1) Auxilium is the asserted holder of the privilege; (2) all redacted or withheld communications were either made by or requested of attorneys in Auxilium's legal department generally or Isabel Duffy specifically; (3) all of the communications were for the purpose of either requesting or conveying legal advice; and (4) the privilege was not waived by including Heartbeat employees in those privileged communications because the Heartbeat employees who were party to the privileged communications were the functional equivalent of Auxilium employees.

Accordingly, Plaintiffs' arguments that the subject communications were either not privileged because they were "indirect" communications or that the privilege was waived as a result of Heartbeat's participation in those communications do not accurately state the parameters of the attorney-client privilege under Pennsylvania law.

1. Pennsylvania law protects indirect privileged communications within a corporation.

Plaintiffs' argument that only direct communications between a lawyer and client are protected (applicable when the client is a person) fails when applied to the attorney-client privilege as it relates to corporations. If Plaintiffs' argument is an accurate statement of the law, in-house counsel could only preserve the privilege by engaging in a series of one-on-one conversations with individual employees instead of communicating to a group or allowing other



employees to relay the legal advice. That is not the law in Pennsylvania. As Pennsylvania courts have recognized,

[t]he administration of the attorney-client privilege in the case of corporations . . . presents special problems. As an inanimate entity, a corporation must act through agents. A corporation cannot speak directly to its lawyers. Similarly, it cannot directly waive the privilege when disclosure is in its best interest. Each of these actions must necessarily be undertaken by individuals empowered to act on behalf of the corporation.

*Red Vision*, 108 A.3d at 60 (citation omitted). Under Pennsylvania law, when the client is a corporation, “privileged communications may be shared by non-attorney employees in order to relay information requested by attorneys.” *CaremarkPCS*, 254 F.R.D. at 258. Privileged communications may be transmitted between non-attorneys “so that the corporation may be properly informed of legal advice and act appropriately.” *SmithKline Beecham Corp. v. Apotex Corp.*, 232 F.R.D. 467, 477 (E.D. Pa. 2005) (citation omitted). The real inquiry is whether the communications were made for the purposes of securing legal advice. *CaremarkPCS*, 254 F.R.D. at 257 (applying Pennsylvania state law to find that the privilege attaches to a document authored by a non-attorney employee to other employees because the communication relayed legal advice from counsel).<sup>6</sup>

Moreover, it is well-established under Pennsylvania law that “where the client is a corporation, the privilege extends to communications between its attorney and *agents* or employees authorized to act on its behalf.” *Exec. Risk Indem., Inc. v. Cigna Corp.*, 81 Pa. D. & C.4th 410 (Com. Pl. 2006) (emphasis added) (favorably citing to *Upjohn Company v. United States*, 449 U.S. 383 (1981)); *Yocabet v. UPMC Presbyterian*, 2015 PA Super 132 (2015)

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<sup>6</sup> This issue has been addressed by federal courts interpreting Pennsylvania law but the Pennsylvania Supreme Court has not had an opportunity to address this issue.

(finding that the attorney-client privilege extends to communications between a corporation's attorney and its agents or employees).

Finally, contrary to the PSC's argument, not all the withheld communications are indirect communications. *See* Pls.' Br. 9. The redactions on log entries 7 and 8 are *direct* communications between Isabel Duffy, an in-house lawyer at Auxilium, and Team Testim® employees (team members from both Auxilium and Heartbeat) conveying legal advice concerning the proposed marketing materials for Testim®. The "indirect" communications on the Privilege Log are the 4 withheld documents (log entries 12 to 15), which are emails conveying the legal advice of Auxilium's in-house counsel, Isabel Duffy, to Team Testim® regarding the marketing materials; the redactions in log entries 1, 2, 3, 4, 5, 6, 9, 10 and 11 are legal advice from or to other attorneys in Auxilium's legal department concerning the marketing materials for Testim® conveyed to or from the collaborative Auxilium/Heartbeat team. Although plaintiffs contend that such communications are not privileged simply because an attorney does not appear in the "To," "From," or "CC" fields of the withheld email, there is no such requirement under Pennsylvania law. Because all of the communications identified on the Privilege Log were made for the purpose of relaying legal advice to the Auxilium and Heartbeat employees responsible for creating marketing materials for Testim®, they are privileged communications protected by the attorney-client privilege and, therefore, are protected from production.

2. Auxilium did not waive the attorney-client privilege by communicating directly with Heartbeat employees because those Heartbeat employees were the “functional equivalent” of Auxilium employees.

There is no valid argument that Auxilium waived the attorney-client privilege by communicating directly to certain employees of Heartbeat.<sup>7</sup> There can be no dispute that the privileged communications identified on the Privilege Log were made as part of the collaborative relationship between Auxilium and Heartbeat by which Auxilium outsourced some of the functions relating to the development of the marketing materials for Testim® instead of hiring employees for that purpose. As long as the Heartbeat employees performing this function were the functional equivalent of Auxilium employees, there was no waiver of the attorney-client privilege. While no Pennsylvania state court has addressed this issue, judges in the Eastern District of Pennsylvania — sitting with diversity jurisdiction in cases involving Pennsylvania-based parties — have consistently recognized the “functional equivalent” doctrine as a basis to uphold claims of attorney-client privilege with respect to communications between pharmaceutical companies and their marketing consultants (and in turn, rejected any argument of waiver). In addition, application of the “functional equivalent” doctrine is consistent with Pennsylvania state court decisions involving claims of privilege waiver.<sup>8</sup>

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<sup>7</sup> As the proponent of the waiver, plaintiffs bear the burden of establishing waiver. *See Pennsylvania Dep’t of Educ. v. Bagwell*, 114 A.3d 1113, 1123-24 (Pa. Commw. 2015).

<sup>8</sup> In fact, Pennsylvania courts routinely cite and rely on federal decisions for novel issues. *See, e.g., Trach v. Fellin*, 817 A.2d 1102, 1115 (Pa. Super. 2003) (finding federal case law persuasive in reaching its decision); *Red Vision*, 108 A.3d at 60 (finding that although federal court cases are not binding, the court may consider such cases persuasive).

- a. Application of the “functional equivalent” doctrine eliminates the issue of waiver regarding confidential privileged communications to independent contractor consultants.

The “functional equivalent” doctrine protects privileged communications between an organization and a nonemployee as long as the non-employee is the functional equivalent of an employee of the organization claiming the privilege. The doctrine arose after the Supreme Court’s decision in *Upjohn*, 449 U.S. 383 (1981), in which the Court abandoned the “control group” test for the “subject matter” test to determine whether corporate communications are privileged. In *Upjohn*, the Supreme Court reasoned that the control group test (1) only extended the attorney-client privilege to managers and directors of the corporation; (2) made it difficult for corporate attorneys to formulate sound advice; (3) was difficult to apply in practice; and (4) did not serve the purpose of the attorney-client privilege, which was to “encourage full and frank communication between attorneys and their clients. . . .” *See Upjohn*, 449 U.S. at 389. The Supreme Court further reasoned that “[t]he attorney’s advice will also frequently be more significant to noncontrol employees than to those who officially sanction the advice, and the control group test makes it more difficult to convey full and frank legal advice to the employees who will put into effect the client corporation’s policy.” *Upjohn*, 449 U.S. at 384. In sum, the Court held that the status of the employee vis-à-vis the corporation claiming the privilege is not dispositive of whether the attorney-client privilege applies, and that instead, the application of privilege must be determined on a case-by-case basis. *See Upjohn*, 449 U.S. at 392 (1981).

Soon after *Upjohn*, Pennsylvania abandoned the control group test for the subject matter test with the same reasoning articulated by the Supreme Court. *See Haggerty v. Yamaha Motor Corp.*, 3 Pa. D. & C.4th 499, 502-03 (Com. Pl. 1989) (relying on the reasoning in *Upjohn* in finding that the title of the employee is not dispositive of whether the attorney-client privilege

attaches). Indeed, Pennsylvania courts routinely cite to and rely on the principles articulated in the Supreme Court decision in *Upjohn*. See, e.g., *Custom Designs*, 39 A.3d at 377 (finding that recent Pennsylvania state court decisions as well as federal court decisions in Pennsylvania “present a consistent and coherent application of *Upjohn*”); *Nat’l R.R. Passenger Corp. v. Fowler*, 788 A.2d 1053, 1064 (Pa. Commw. 2001) (applying the reasoning of *Upjohn* to determine that the attorney-client privilege applied to communications with employees irrespective of title); *Gould v. City of Aliquippa*, 750 A.2d 934 (Pa. Commw. 2000) (relying on *Upjohn* in determining that oral statements taken by the City’s attorney from City employees authorized to act on behalf of the City were protected by attorney-client privilege); *Gillard v. AIG Ins. Co.*, 15 A.3d 44, 57 (Pa. 2011) (relying on *Upjohn* in determining that the attorney-client privilege affords derivative protection for communications from the attorney to the client). In addition, Pennsylvania courts recognize that it is the scope of employment that is relevant to the privilege analysis. See *CaremarkPCS*, 254 F.R.D. at 258.

Moreover, at least one Pennsylvania appellate court has declined to limit the application of the privilege to corporate employees when it recently found that the privilege extended to communications among the board of directors of a corporation. See *Yocabet*, 2015 PA Super 132. Although the *Yocabet* court did not specify that it was applying the “functional equivalent” test by name, it reasoned that “where a representative for a corporation acts within the scope of his or her employment or *agency*, the representative and the corporation are one and the same entity. . . .” *Yocabet*, 2015 PA Super 132, at \*12 (emphasis added) (citation omitted).

Although the Pennsylvania state courts have not specifically addressed the “functional equivalent” doctrine in the context at issue here,<sup>9</sup> judges in the Eastern District of Pennsylvania have adopted the “functional equivalent” doctrine to hold that there is no waiver of the attorney-client privilege when pharmaceutical manufacturers communicate legal advice to their consultants hired to develop marketing campaigns.

In *In re Flonase*, 879 F. Supp. 2d at 457, GlaxoSmithKline (GSK) hired a national pharmaceutical consulting firm, Swiftwater, to help launch the marketing campaign for its product Flonase. Plaintiffs in that case sought the production of privileged communications between GSK and Swiftwater. The court determined that GSK did not waive the privilege by communicating directly with Swiftwater because Swiftwater was the functional equivalent of an employee of GSK. In reaching that conclusion, the court held that the purpose of the attorney-client privilege is to “encourage full and frank communication between attorneys and their clients and thereby promote broader public interests in the observance of law and administration of justice.” *In re Flonase*, 879 F. Supp. 2d at 457 (relying on the Supreme Court’s reasoning in *Upjohn*).<sup>10</sup> In keeping with that purpose, “whether the attorney-client privilege applies shall be

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<sup>9</sup> Plaintiff’s reliance on *Bagwell*, 114 A.3d at 1115 is misplaced. Most importantly, at the outset of the decision, the court makes clear that because the certified record was deficient, the court would hold its decision in abeyance “as to the attorney privileges” until it had a complete record. *See Id.* at 1115. In addition, the facts of *Bagwell* do not lend themselves to a “functional equivalent” analysis. Penn State as an institution cannot be the functional equivalent of an employee of the Department of Education simply because the Secretary of that department is also a member of the Penn State Board of Trustees. The “functional equivalent” doctrine does not protect privileged communications to a third party who is only tenuously connected to the organization asserting the privilege. Instead, the “functional equivalent” doctrine requires that the third party and corporation be so connected that the third party is essentially an employee of the corporation.

<sup>10</sup> It is important to note that, in *Flonase*, GSK was headquartered in Pennsylvania, the court was sitting in diversity jurisdiction and plaintiffs had raised both state and federal claims. The court in *Flonase* also applied Pennsylvania state law in prior attorney-client privilege  
(continued...)

determined on a case-by-case basis looking at the reasons for the communication, rather than the status of the employee.” *In re Flonase*, 879 F. Supp. 2d at 457. Specifically, the focus of the inquiry is on whether the communications were kept confidential and made for the purpose of obtaining or providing legal advice. *See Id.* at 460.

In particular, and relevant to the issues here, in reaching its decision that Swiftwater was the functional equivalent of an employee of GSK, the court in *Flonase* relied on four essential facts:

1. Swiftwater was an integrated member of the brand maturation team, which included full-time GSK employees;
2. Swiftwater played a significant role in the team, assisting in an administrative, managerial and analytic capacity;
3. Swiftwater was intimately involved in the creation, development and implementation of the Flonase brand maturation plan; and
4. The documents and communications between Swiftwater and GSK remained confidential throughout the collaborative process.

*See In re Flonase*, 879 F. Supp. 2d at 460 (E.D. Pa. 2012).

In 2013, a year after *Flonase*, another judge in the Eastern District of Pennsylvania again applied the “functional equivalent” doctrine in *King Drug*, 2013 WL 4836752 (E.D. Pa. Sept. 11, 2013). In *King Drug*, the pharmaceutical company Cephalon hired a consulting firm, Clarion, to help its employees in developing a plan to maximize the commercial success of certain drugs. There was a Business Strategy Team that consisted of both Clarion and Cephalon employees who had daily contact with each other, and Clarion consultants had office space at Cephalon. *See King Drug*, 2013 WL 4836752 at \*5 (E.D. Pa. Sept. 11, 2013). Clarion also frequently had

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disputes between the parties. *See In re Flonase*, 723 F. Supp. 2d 761, 764 (E.D. Pa. 2010) (applying Pennsylvania law in holding that the attorney-client privilege protects privileged communications with former employees.).

to consult Cephalon's in-house counsel on regulatory matters. Citing *Flonase*, the *King Drug* court held that Clarion served as the functional equivalent of Cephalon employees.

In particular, the *King Drug* court founded its analysis on facts almost identical to those relied upon by the court in *Flonase*:

1. Clarion was an integrated member of the Brand Strategy team;
2. Clarion worked closely with Cephalon employees to provide managerial support and strategic advice;
3. Clarion participated in making presentations to Cephalon senior management; and
4. Clarion was subject to a confidentiality agreement and the documents remained confidential.

*See King Drug*, 2013 WL 4836752 at \*6 (E.D. Pa. Sept. 11, 2013). The court reasoned that the simple formality of distinguishing an employee on the corporate payroll from an independent contractor does not diminish the need for in-house counsel and nonlawyers to collaborate to ensure compliance with the law. Relying on the Supreme Court's reasoning in *Upjohn*, the court concluded that the focus of the analysis should be whether the communication to the consultant was kept confidential and made for the purpose of providing or obtaining legal advice. *See King Drug*, 2013 WL 4836752, at \*6 (E.D. Pa. Sept. 11, 2013). As a result, the court held that "where a consultant performs a similar role to an employee, confidential communications made for the purpose of obtaining or providing legal advice should be subject to the attorney-client privilege regardless of whether the consultant was hired for a litigation or business purpose." *King Drug*, 2013 WL 4836752, at \*7 (E.D. Pa. Sept. 11, 2013).<sup>11</sup>

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<sup>11</sup> The majority of courts that have addressed this issue have adopted similar approaches and found a consultant to be the functional equivalent of an employee. *See, e.g., Smith v. Unilife Corp.*, No. 13-5101, 2015 WL 667432, at \*3 (E.D. Pa. Feb. 13, 2015) (holding communications with an independent consultant were privileged where the defendant corporation had relied on the consultant to make recommendations to the general counsel); *Stafford Trading, Inc. v. Lovely*, No. 05-4868, 2007 WL 611252, at \*7 (N.D. Ill. Feb. 22, 2007) (adopting a "balanced  
(continued...)



The “functional equivalent” doctrine, as articulated in both *Flonase* and *King Drug*, is consistent with Pennsylvania’s longstanding adherence to the Supreme Court’s reasoning in *Upjohn* and is also consistent with Pennsylvania’s case law that the titles of the people privy to the communication are not dispositive of whether the privilege applies — it is whether the communication was intended to remain confidential and was within the scope of the employment or agency. *See CaremarkPCS*, 254 F.R.D. at 258.

b. Heartbeat was the functional equivalent of an employee.

Plaintiffs have failed to meet their burden to prove that Auxilium waived its attorney-client privilege<sup>12</sup> when it communicated with Heartbeat regarding privileged legal advice because Plaintiffs **cannot** demonstrate that (1) Heartbeat acted in any capacity other than as the functional equivalent of an Auxilium employee, (2) that the Heartbeat employees were not under the same confidentiality obligations as their Auxilium colleagues, or (3) that the Heartbeat employees failed to keep those privileged communications confidential. The PSC’s waiver argument is premised on the *ipse dixit* conclusion that Heartbeat was not the functional equivalent of an Auxilium employee. The PSC has chosen to ignore over 10,000 documents that Auxilium produced on behalf of Heartbeat demonstrating the Heartbeat-Auxilium agency

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approach and extending the privilege to instances where the independent consultant and the corporation communicated for the purpose of obtaining or providing confidential legal advice); *U.S. ex rel. Strom v. Scios, Inc.*, No. C05–3004, 2011 WL 4831193, at \*4 (N.D.Cal. Oct. 12, 2011) (declining to reconsider a decision finding that a consultant was the functional equivalent of an employee); *U.S. ex rel. Fry v. Health Alliance of Greater Cincinnati*, No. 1:03–167, 2009 WL 5033940, at \*4 (S.D. Ohio Dec. 11, 2009) (“As long as the independent contractor has a role similar to that of an employee . . . , communications between the contractor and attorneys for the purpose of seeking legal advice are privileged.”).

<sup>12</sup> Once it is established that the privilege was properly invoked with respect to communications involving legal advice, the burden shifts to the party alleging waiver to prove that the attorney-client privilege was waived. *See Red Vision*, 108 A.3d at 62.

relationship. Moreover, the PSC cannot find support for their rhetorical argument in the over one million documents produced by Auxilium to date.

As such, Plaintiff has not, and cannot, carry its burden to establish that Heartbeat was *not* the functional equivalent of an Auxilium employee. The record establishes that Heartbeat worked closely with Auxilium employees to develop the marketing materials for Testim® and as an integrated member of Team Testim®. *See* Ex. 5, HEARTBEATS-MDL2545-00022433-34. Year after year, Heartbeat was delegated the task of developing new content, rationalizing existing content on the website and tracking the performance of the Testim® website in collaboration with Auxilium employees and with legal and regulatory input and advice from Auxilium's in-house attorneys. *See* Ex. 2, HEARTBEATS-MDL2545-00017282; Ex. 4, HEARTBEATS MDL-2545-00017973; Ex. 17, HEARTBEATS-MDL2545-00023178; Ex. 3, HEARTBEATS-MDL2545-00023291. Heartbeat participated regularly in Auxilium PRC meetings and brainstorming sessions, in which Auxilium lawyers participated for the purpose of providing legal and regulatory guidance and advice. *See* Ex. 6, HEARTBEATS-MDL2545-00000046. Heartbeat received instruction directly from Auxilium in-house attorneys and other key members of the PRC regarding changes that needed to be made to marketing materials for the purpose of legal and regulatory compliance. *See* Ex. 10, HEARTBEATS-MDL2545-00005519. Heartbeat worked directly with Auxilium employees to ensure that all of the marketing materials met all regulatory and legal requirements and was consistent with the Testim® brand message. *See e.g.*, Ex. 18, Declaration of Kristin Kennedy; Ex. 10, HEARTBEATS-MDL2545-00005519; Ex. 12, HEARTBEATS-MDL2545-00002220-21.

Notably, it was always required and expressly understood that the communications between Heartbeat and Auxilium remain confidential. The terms of the Consultant Agreement,

entered into on May 9, 2009 by Auxilium and Heartbeat, provide that all information and communications were deemed to be confidential. Indeed, Heartbeat agreed that the documents remain confidential even after the termination of the relationship. *See* Ex. 1, HEARTBEATS-MDL2545-00015960. In keeping with its confidentiality obligations, when served with Plaintiff's subpoena, Heartbeat notified Auxilium of the request and the parties endeavored to comply with the subpoena while Auxilium asserted its rights to claim privilege with respect to attorney-client communications.

In sum, consistent with the operative facts in both *Flonase* and *King Drug*, Heartbeat was the functional equivalent of an Auxilium employee because:

1. Heartbeat was an integrated member of Team Testim®;
2. Heartbeat developed the marketing materials for Testim®;
3. Heartbeat regularly participated in PRC meetings so that it could address any legal, regulatory or marketing issues related to the promotional pieces; and
4. At all times Heartbeat sought to protect the confidentiality of the communications.

Accordingly, as in *Flonase* and *King Drug*, and consistent with Pennsylvania law that follows the *Upjohn* analysis regarding the application of privilege, the communication of confidential legal advice to Heartbeat for the purpose of insuring that Auxilium's marketing material complied with applicable laws and regulations did not constitute a waiver of Auxilium's attorney-client privilege with respect to the fifteen documents at issue.

#### IV. CONCLUSION

For all of these reasons, defendant Auxilium Pharmaceuticals, Inc. respectfully requests that the Court deny the PSC's Motion to Compel Privilege Log Information and sustain the assertion of privilege with respect to the communications at issue. In the alternative, it is respectfully requested that the Court conduct an *in camera* review of the communications at issue to verify that the assertion of privilege by Auxilium Pharmaceuticals, Inc. was proper.

Dated: August 28, 2015

Respectfully submitted,

AUXILIUM PHARMACEUTICALS, INC..

/s/ Andrew K. Solow

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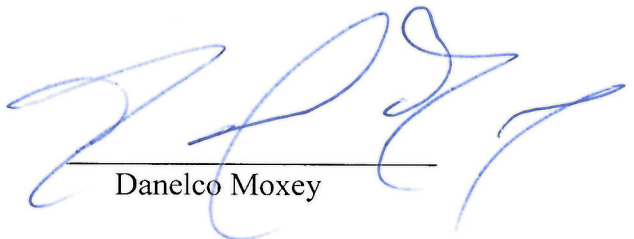
**CERTIFICATE OF SERVICE**

I certify that on August 28, 2015, a copy of:

1. Auxilium Pharmaceuticals Inc.'s Brief in Opposition to Plaintiffs' Steering Committee's Motion to Compel Privilege Log Information; and
2. Declaration of Andrew K. Solow in Support of Defendant Auxilium Pharmaceuticals, Inc.'s Brief in Opposition of Plaintiffs' Steering Committee's Motion to Compel Privilege Log Information together with all exhibits attached thereto

were served electronically on counsel of record for all parties through the Court's CM/ECF system.

Dated: August 28, 2015



Danelco Moxey